

House File 204

HOUSE FILE _____
BY FORD

Passed House, Date _____ Passed Senate, Date _____
Vote: Ayes _____ Nays _____ Vote: Ayes _____ Nays _____
Approved _____

A BILL FOR

1 An Act relating to fair market drug pricing including the
2 establishment of a prescription card program.
3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:
4 TLSB 2035HH 82
5 pf/cf/24

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1 1 Section 1. FAIR MARKET DRUG PRICING == LEGISLATIVE
1 2 FINDINGS. The general assembly finds that:
1 3 1. In this time of economic difficulty, the state of Iowa
1 4 needs to maximize its financial resources in order to provide
1 5 the maximum amount of health care coverage possible for low=
1 6 income residents. Now more than ever, the state of Iowa needs
1 7 to lower the prices it pays for prescription drugs.
1 8 2. Many Iowans are uninsured or underinsured for
1 9 prescription drug coverage and do not qualify for medical
1 10 assistance. These uninsured or underinsured Iowans pay
1 11 excessive prices for prescription drugs. In many cases, these
1 12 excessive drug prices have the effect of denying Iowans access
1 13 to medically necessary care, thereby threatening their health
1 14 and safety.
1 15 3. Among these uninsured and underinsured Iowans, many
1 16 require repeated doctor or medical clinic appointments, with
1 17 their health having degenerated because they cannot afford the
1 18 drugs prescribed for them. Many are admitted to or treated at
1 19 hospitals each year because they cannot afford the drugs
1 20 prescribed for them that could have prevented the need for
1 21 hospitalization. Many others enter expensive institutional
1 22 care settings because they cannot afford the prescription
1 23 drugs that could have supported them outside of an
1 24 institution. In each of these circumstances, uninsured and
1 25 underinsured Iowans too often become medical assistance
1 26 recipients because of their inability to afford prescription
1 27 drugs. Therefore, helping secure lower drug prices for
1 28 uninsured and underinsured Iowans directly benefits and
1 29 supports the medical assistance program.
1 30 4. The state is the only agent that, as a practical
1 31 matter, can play an effective role as a market participant on
1 32 behalf of all Iowans who are uninsured, underinsured, or are
1 33 medical assistance program beneficiaries. The state already
1 34 provides drugs and acts as a prescription benefits manager for
1 35 a variety of programs, and should expand that role to
2 1 negotiate voluntary drug rebates, using these funds to
2 2 maintain and expand medical assistance services while offering
2 3 lower drug prices to the uninsured and underinsured who do not
2 4 qualify for medical assistance.
2 5 Sec. 2. NEW SECTION. 249A.36 FAIR MARKET DRUG PRICING
2 6 PROGRAM.
2 7 1. PURPOSE. Recognizing that the state already acts as a
2 8 prescription benefits manager for a variety of health plans
2 9 and assistance programs, the purpose of this section is to
2 10 provide prescription drug coverage to new populations by
2 11 expanding the state's role as a participant in the
2 12 prescription drug marketplace, negotiating voluntary rebates
2 13 from drug companies, and using the funds to make prescription
2 14 drugs more affordable to the state medical assistance program
2 15 and to Iowans. Such a program will improve public health and
2 16 welfare, promote the economic strength of our society, and
2 17 both directly and indirectly benefit the state medical
2 18 assistance program.
2 19 2. DEFINITIONS. As used in this section, unless the
2 20 context otherwise requires:

2 21 a. "Federal poverty level" means the federal poverty level
2 22 as defined by the most recently revised poverty income
2 23 guidelines published by the United States department of health
2 24 and human services.
2 25 b. "Labeler" means a person that receives prescription
2 26 drugs from a manufacturer or wholesaler and repackages those
2 27 drugs for later retail sale, and that has a labeler code from
2 28 the federal food and drug administration under 21 C.F.R. }
2 29 207.20.

2 30 c. "Manufacturer" means a manufacturer of prescription
2 31 drugs as defined in 42 U.S.C. } 1396r-8(k)(5), including a
2 32 subsidiary or affiliate of a manufacturer.

2 33 d. "Participating retail pharmacy" means a retail pharmacy
2 34 or other business licensed to dispense prescription drugs in
2 35 this state that participates in the state medical assistance
3 1 program, or voluntarily agrees to participate in the
3 2 prescription card program.

3 3 e. "Wholesaler" means wholesaler as defined in section
3 4 155A.3.

3 5 3. DRUG DISCOUNT AND REBATE AGREEMENTS.

3 6 a. In addition to negotiating rebates with drug
3 7 manufacturers pursuant to section 249A.20A, the director shall
3 8 negotiate other discount prices or rebates for prescription
3 9 drugs from drug manufacturers and labelers for the
3 10 prescription card program and other state programs that pay
3 11 for or acquire prescription drugs. A drug manufacturer or
3 12 labeler that sells prescription drugs in this state may
3 13 voluntarily elect to negotiate any of the following:

3 14 (1) Supplemental rebates for the medical assistance
3 15 program over and above those required under 42 U.S.C. } 1396r-
3 16 8 as provided in section 249A.20A.

3 17 (2) Discount prices or rebates for the prescription card
3 18 program.

3 19 (3) Discount prices or rebates for any other state program
3 20 that pays for or acquires prescription drugs.

3 21 b. In negotiating discount prices and rebate terms, the
3 22 director shall take into consideration the rebate calculated
3 23 under the medical assistance rebate program pursuant to 42
3 24 U.S.C. } 1396r-8, any rebate negotiated pursuant to section
3 25 249A.20A, the price provided to eligible entities under 42
3 26 U.S.C. } 256b, and any other available information on
3 27 prescription drug prices, discounts, and rebates.

3 28 c. (1) The director shall determine whether to include
3 29 the products in the formularies or prior authorization
3 30 programs for any state program that pays for or acquires
3 31 prescription drugs, taking into consideration the following:

3 32 (a) The director and a drug manufacturer or labeler fail
3 33 to reach agreement on the terms of a supplemental rebate under
3 34 the medical assistance program or a discount or rebate for the
3 35 prescription card program.

4 1 (b) The discounts or rebates offered by the manufacturer
4 2 or labeler are not as favorable to the state as the prices
4 3 provided to eligible entities under 42 U.S.C. } 256b.

4 4 (2) The names of manufacturers and labelers that do not
4 5 enter into discount pricing or rebate agreements under this
4 6 section are public information and the department shall
4 7 release this information to the public and actively distribute
4 8 the information to doctors, pharmacists, and other health
4 9 professionals.

4 10 4. PRESCRIPTION CARD PROGRAM ESTABLISHED.

4 11 a. The department shall establish the prescription card
4 12 program as a state pharmaceutical assistance program under 42
4 13 U.S.C. } 1396r-8(c)(1)(C), to provide discounts to
4 14 participants for drugs covered by a rebate agreement. Using
4 15 funds from negotiated rebates, the department shall contract
4 16 with wholesalers and participating retail pharmacies to
4 17 deliver discounted prices to prescription card program
4 18 participants.

4 19 b. The drug discounts received by prescription card
4 20 program participants shall be calculated by the director on a
4 21 quarterly basis. That calculation shall provide discounts
4 22 approximately equal to the average amount of the negotiated
4 23 drug rebate minus an amount to cover the reasonable
4 24 administrative costs of the prescription card program.

4 25 c. (1) An individual is eligible to participate in the
4 26 prescription card program if the individual is a resident of
4 27 Iowa and has a net family income below three hundred fifty
4 28 percent of the federal poverty level.

4 29 (2) An individual is ineligible to participate in the
4 30 prescription card program if the individual is eligible for
4 31 assistance under the medical assistance program or is covered

4 32 by an insurance policy that provides benefits for prescription
4 33 drugs equal to or greater than the benefits provided under the
4 34 prescription card program, as specified by rules adopted by
4 35 the director.

5 1 d. The department shall establish simple procedures for
5 2 enrolling prescription card program participants and shall
5 3 undertake outreach efforts to build public awareness of the
5 4 program and maximize enrollment by eligible residents.

5 5 e. (1) The department shall adopt rules requiring
5 6 disclosure by participating retail pharmacies to prescription
5 7 card program participants of the amount of savings provided as
5 8 a result of the prescription card program. The rules shall
5 9 include provisions to protect information that is proprietary
5 10 in nature.

5 11 (2) A participating retail pharmacy shall verify to the
5 12 department the amounts charged to prescription card program
5 13 participants and nonparticipants, and shall provide the
5 14 department with utilization data necessary to calculate
5 15 rebates from manufacturers and labelers. The department shall
5 16 protect the confidentiality of all information subject to
5 17 confidentiality protection under state or federal law, rule,
5 18 or regulation. The department shall not impose transaction
5 19 charges on wholesalers or participating retail pharmacies that
5 20 submit claims or receive payments under the program.

5 21 (3) Wholesalers and participating retail pharmacies shall
5 22 be paid in advance for prescription card discounts or shall be
5 23 reimbursed by the department on a biweekly basis.

5 24 f. The department may require a wholesaler or
5 25 participating retail pharmacy to segregate drugs under the
5 26 prescription card program from other drug inventory. The
5 27 department may require a wholesaler or participating retail
5 28 pharmacy to maintain records of acquisition and disposition of
5 29 drugs under the prescription card program separately from the
5 30 wholesaler's or pharmacy's other records.

5 31 g. Disputes or discrepancies in rebate amounts shall be
5 32 resolved using the following process:

5 33 (1) If there is a discrepancy in the manufacturer's or
5 34 labeler's favor between the amount claimed by a pharmacy and
5 35 the amount rebated by the manufacturer or labeler, the
6 1 department, at the department's expense, may hire a mutually
6 2 agreed upon independent auditor. If a discrepancy still
6 3 exists following the audit, the manufacturer or labeler shall
6 4 justify the reason for the discrepancy or make payment to the
6 5 department for any additional amount due.

6 6 (2) If there is a discrepancy against the interest of the
6 7 manufacturer or labeler in the information provided by the
6 8 department to the manufacturer or labeler regarding the
6 9 manufacturer's or labeler's rebate, the manufacturer or
6 10 labeler, at the manufacturer's or labeler's expense, may hire
6 11 a mutually agreed upon independent auditor to verify the
6 12 accuracy of the data supplied to the department. If a
6 13 discrepancy still exists following the audit, the department
6 14 shall justify the reason for the discrepancy or provide a
6 15 refund to the manufacturer or labeler.

6 16 (3) Following the procedures established in subparagraph
6 17 (1) or (2), either the department or the manufacturer or
6 18 labeler may request a hearing. Supporting documentation shall
6 19 accompany the request for a hearing.

6 20 h. Discounts to participants in the prescription card
6 21 program shall begin no later than January 1, 2008.

6 22 5. ADMINISTRATION.

6 23 a. The department shall report the enrollment and
6 24 financial status of the prescription card program and report
6 25 savings from any supplemental medical assistance program
6 26 rebates and any other discounts or rebates to the general
6 27 assembly by February 1, annually.

6 28 b. If the director determines that it is beneficial to
6 29 both the prescription card program and another state program
6 30 to combine drug pricing negotiations to maximize discount
6 31 pricing and drug rebates, the director shall work with the
6 32 other state program to do so.

6 33 c. The department shall adopt rules to implement this
6 34 section.

6 35 d. The department shall seek any waivers of federal law,
7 1 rule, or regulation necessary to implement the provisions of
7 2 this section.

7 3 e. The department shall administer this section in a
7 4 manner that benefits the greatest number of residents while
7 5 remaining in compliance with federal law and regulations. If
7 6 necessary, the director may separate medical assistance
7 7 program negotiations from nonmedical assistance program

7 8 negotiations and preferred drug list decisions, or may limit
7 9 participation in the prescription card program to reduce the
7 10 number of participants.

7 11 EXPLANATION

7 12 This bill directs the director of human services, in
7 13 addition to negotiating rebates with drug manufacturers
7 14 pursuant to the Medicaid preferred drug list program, to
7 15 negotiate other discount prices or rebates for prescription
7 16 drugs from drug manufacturers and labelers for the
7 17 prescription card program and other state programs that pay
7 18 for or acquire prescription drugs.

7 19 The bill provides that the director is to determine whether
7 20 to include the products of labelers and manufacturers in the
7 21 formularies or prior authorization programs for any state
7 22 program that pays for or acquires prescription drugs, taking
7 23 into consideration: (a) if the director and a drug
7 24 manufacturer or labeler fail to reach agreement on the terms
7 25 of a supplemental rebate under the medical assistance program
7 26 or a discount or rebate for the prescription card program; or
7 27 (b) whether the discounts or rebates offered by the
7 28 manufacturer or labeler are not as favorable to the state as
7 29 the prices provided to eligible entities under 42 U.S.C. }
7 30 256b. The bill also provides that the names of manufacturers
7 31 and labelers that do not enter into discount pricing or rebate
7 32 agreements are public information and the department of human
7 33 services is to release this information to the public and
7 34 actively distribute the information to doctors, pharmacists,
7 35 and other health professionals.

8 1 The bill establishes the prescription card program as a
8 2 state pharmaceutical assistance program to provide discounts
8 3 to participants for drugs covered by a rebate agreement.
8 4 Using funds from negotiated rebates, the department is
8 5 directed to contract with wholesalers and participating retail
8 6 pharmacies to deliver discounted prices to prescription card
8 7 participants. An individual is eligible to participate in the
8 8 prescription card program if the individual is a resident of
8 9 Iowa and has a net family income below 350 percent of the
8 10 federal poverty level. An individual is ineligible to
8 11 participate in the prescription card program if the individual
8 12 is eligible for assistance under the medical assistance
8 13 program or is covered by an insurance policy that provides
8 14 benefits for prescription drugs equal to or greater than the
8 15 benefits provided under the prescription card program. The
8 16 bill directs the department to establish simple procedures for
8 17 enrolling prescription card program participants and to
8 18 undertake outreach efforts to build public awareness of the
8 19 program and maximize enrollment by eligible residents. The
8 20 bill directs the department to adopt rules requiring
8 21 disclosure by participating retail pharmacies to prescription
8 22 card program participants of the amount of savings provided as
8 23 a result of the prescription card program. The rules are to
8 24 include provisions to protect information that is proprietary
8 25 in nature. The bill specifies requirements for participating
8 26 retail pharmacies and wholesalers, provides for payment of
8 27 wholesalers and participating retail pharmacies, and provides
8 28 a process for addressing discrepancies or disputes in rebate
8 29 amounts. The bill provides that discounts to participants in
8 30 the prescription card program are to begin no later than
8 31 January 1, 2008.

8 32 The bill directs the department to report the enrollment
8 33 and financial status of the prescription card program and
8 34 report savings from any supplemental medical assistance
8 35 program rebates and any other discounts or rebates to the
9 1 general assembly by February 1, annually; provides that if the
9 2 director determines that it is beneficial to both the
9 3 prescription card program and another state program to combine
9 4 drug pricing negotiations to maximize discount pricing and
9 5 drug rebates, the director shall work with the other state
9 6 program to do so; directs the department to adopt rules to
9 7 implement the provisions of the bill; directs the department
9 8 to seek any waivers of federal law, rule, or regulation
9 9 necessary to implement the provisions of the bill; directs the
9 10 department to administer the bill in a manner that benefits
9 11 the greatest number of residents while remaining in compliance
9 12 with federal law and regulation; and provides that if
9 13 necessary the director may separate medical assistance program
9 14 negotiations from nonmedical assistance program negotiations
9 15 and preferred drug list decisions, or may limit participation
9 16 in the prescription card program to reduce the number of
9 17 participants.

